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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,001	09/12/2003	John B. Slate	11102.2.1	8607

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,001	SLATE ET AL.	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/2004,2/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 99' (Figure 10D). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Slate et al (U.S. patent No. 5,911,703). Slate et al disclose a needle-free injector that

includes a drive mechanism having a ram (56) where the injection is performed in two stages. The first stage is the injection stage where an impulse or partial dose of fluid medicament is injected from an impulse chamber (70) through a nozzle (76) and into the patient at a first fluid pressure. The second stage is the perfusion stage where the remainder of the fluid medicament is slowly infused into the patient at a second fluid pressure. As shown in Figure 6, the remainder dose is infused from a reservoir (26) through the nozzle and into the patient. In lines 5-59 of column 10, Slate et al disclose that the fluid pressure during the injection stage is much higher than the fluid pressure during the infusion stage and, in Figure 9, show that first fluid pressure is at least five times greater than the second fluid pressure. The injection and infusion steps are performed sequentially to provide a continuous flow of fluid medicament to the patient. The injection is accomplished using an impulse generator having a plunger (28) and a ram (56).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landau (U.S. Patent No. 6,645,170) in view of Slate et al (U.S. Patent No. 5,911,703). Landau discloses a needle-free injection method for engaging a glass reservoir or pre-

filled cartridge (60) which is in fluid communication with a body member (12) and where the body member has a fluid pathway with a first opening (65) and a second opening (located distally of the ball valve in Figure 10) which is in fluid communication with an impulse chamber (58) (see Figures 2 and 10). Fluid communication between the impulse chamber and the second opening is established as shown in Figures 2 and 4 when the ball valve (62) is moved forward and the fluid flows through the conduits (64). Landau teaches transferring a partial dose into the impulse chamber as seen in Figure 5 where a remainder dose (57) is initially left in the reservoir. The partial dose in the impulse chamber is injected through the nozzle (54) while the plunger (66) is pushed and then the remainder dose is infused from the reservoir and through the nozzle when the plunger is in the position shown in Figure 6. The injection is accomplished using an impulse generator having a plunger (66) and a ram (70). The injection and infusion steps are performed sequentially to provide a continuous flow of fluid medicament to the patient.

Landau thus discloses the method claims substantially as claimed. However, Landau is silent on the partial dose being injected at a fluid pressure that is greater than the fluid pressure at which the remainder dose is infused. Slate et al disclose a needle-free injector that includes a drive mechanism having a ram (56) where the injection is performed in two stages. The first stage is the injection stage where an impulse or partial dose of fluid medicament is injected into the patient at a first fluid pressure. The second stage is the perfusion stage where the remainder of the fluid medicament is slowly infused into the patient at a second fluid pressure. In lines 5-59 of column 10,

Slate et al disclose that the fluid pressure during the injection stage is much higher than the fluid pressure during the infusion stage and, in Figure 9, show that first fluid pressure is at least five times greater than the second fluid pressure. In lines 22-40 of column 2, Slate et al teach that it is beneficial to use an injector which infuses the fluid medicament at a lower pressure as it prevents harmful damage to a patient's body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the injector of Landau with the driving mechanism as taught by Slate et al which would allow the remainder dose to be infused at a lower pressure than the pressure at which the initial or partial dose is injected, thus, preventing trauma to a patient's body.

As to claims 2 and 9, Landau shows, in Figure 5, that the remainder dose has a fluid volume that is at least two times greater than the fluid volume of the partial dose. However, as to the limitation of volume in claim 2, Landau or Slate et al are silent as to the volume of the partial dose being in a range between one and twenty microliters. The instant disclosure describes this parameter as being merely preferable and does not describe it as contributing any unexpected result. As such, these parameters are deemed matters of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,652,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed towards fluid medicament injectors.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haber et al (U.S. Patent No. 5,298,023), Roser (U.S. Patent No. 6,224,567), Willis et al (U.S. Patent No. 6,406,455), and Hjertman et al (U.S. Patent No. 6,689,101 disclose injectors. Willis et al teach initial high pressure injections followed by lower pressure infusions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons
6/21/06